K044989

SEP 16 2004

510(k) SUMMARY

Sintea Biotech Anterior Cervical Plate System

Trade Name: Sintea Biotech Anterior Cervical Plate System
Common Name: Anterior Cervical Plate System
Classification Name(s): Appliance, Fixation, Spinal Intervertebral Body Spinal Fixation Device System Class II;
Classification(s): § 888.3060 – Spinal Intervertebral Body Fixation Orthosis
Device Class: Class II for all requested indications
Classification Panel: Orthopedic Device Panel
Product Code(s): KWQ

Applicant Name and Address:

Sintea Biotech, Inc.
407 Lincoln Road, Suite 10L
Miami Beach, FL 33139
(305) 673-6226 FAX (305) 673-3312

Company Contact:
Ms. Marcela Velazquez
Sintea Biotech, Inc.
407 Lincoln Road, Suite 10L
Miami Beach, FL 33139
(305) 673-6226 FAX (305) 673-3312

Performance Standards

Food and Drug Administration mandated Performance Standards for Spinal Intervertebral Body Fixation Device System Class II devices are not in effect. Sintea Biotech, Inc. intends to comply with all voluntary Performance Standards applicable to the Sintea Biotech Anterior Cervical Plate System. At the present time, various performance standards such as ASTM, ISO, QSR/cGMP and in-house SOP standards are used. Sintea Biotech, Inc. also complies with the general controls authorized under Sections 501, 502, 510, 516, 518, 519, and 520 of the Food, Drug and Cosmetic Act. In addition, Sintea Biotech, Srl., which is the location of the manufacturing facility for this device, has earned the CE Mark (number 0546) using the ISO 9001 quality system model, and the Medical Device Directive, and is in good standing with IQNet, their notified body. A declaration of conformity with design controls is also included in this 510(k) submission, signed by the manufacturer, Sintea Biotech, Srl.

Special Controls

Anterior Cervical Plate Systems must comply with the following special controls:

- Compliance with materials standards

- Compliance with mechanical testing standards
- Compliance with biocompatibility standards, and
- Labeling which contains the following statements in addition to other appropriate labeling information:

  WARNING: This device is intended for anterior cervical intervertebral body fusions only.
  WARNING: This device is not approved for screw attachments to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Labeling:
The Sintea Biotech Anterior Cervical Plate System discussed in this premarket notification will be manufactured by Sintea Biotech, and will be labeled as such. The system will be marketed exclusively to healthcare facilities and physicians. In addition, FDA requirements stipulate that the following additional labeling warnings be provided, as noted above:

Warnings:

WARNING: This device is intended for anterior cervical intervertebral body fusions only.
WARNING: This device is not approved for screw attachments to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Surgical Technique:

The surgical approach of the Sintea Biotech Anterior Cervical Plate System is enclosed in Section 8 of this submission, and includes this caution statement:

CAUTION: The Sintea Biotech Anterior Cervical Plate System is made of biocompatible Ti6Al4V ELI titanium alloy. Mixing of dissimilar metals can accelerate the corrosion process. The components of this system must NOT be used with implants of other metals in building a construct. Components of the Sintea Biotech Anterior Cervical Plate System should NOT be used with components from any other system or manufacturer.

Predicate Devices (legally marketed comparison devices):

Sintea Biotech, Inc. believes that the Sintea Biotech Anterior Cervical Plate System is substantially equivalent to Synthes' Cervical Spine Locking Plate (CSLP), K000742 and K000536, (Decision Dates: 03/29/2000 and 03/15/2000, respectively). A basic feature comparison table for the Sintea Biotech Anterior Cervical Plate System and this predicate device is located at the end of this section of the submission.

Device Description:
The Sintea Biotech Anterior Cervical Plate System is a family of anterior cervical spine locking plates, screws and associated instruments, providing an anterior buttress construct for use following Corpectomy or discectomy. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach. It is indicated for traumatic, degenerative, and tumor pathologies.

All system components are made of biocompatible Ti6Al4V ELI titanium alloy, which minimizes the possibility of allergic reaction and enhances post-operative MRI/CT analyses as described by ASTM F136. Do not use any of the Sintea Biotech Anterior Cervical Plate System components with components from any other system or manufacturer.

Intended Use:

The Sintea Biotech Anterior Cervical Plate System is intended for anterior screw fixation of the cervical spine (C3 to C7).

The device is intended for single use only and is packaged non-sterile with sterilization required prior to use.

WARNING: This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Indications for Use:

The Sintea Biotech Anterior Cervical Plate System is indicated for use in the cervical spine (levels C3 to C7) in the following conditions:

- Degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Trauma (fracture or dislocation)
- Spinal stenosis
- Deformities or curvature (scoliosis, kyphosis, lordosis)
- Tumor
- Pseudarthrosis
- Failed previous fusion

Summary of Biomechanical Testing:

Fatigue testing of a worst case system configuration using constructs made of titanium alloy was conducted. The testing demonstrates that when subjected to repeated physiological loads, increased by suitable safety factors, the Sintea Biotech Anterior

Cervical Plate System overcomes both static and fatigue tests, with occurrences of neither microscopic nor macroscopic failures, after five million cycles of repeated applied force, according to the ASTM F1717 test standard. Furthermore, testing of the worst case construct shows that the Sintea Biotech Anterior Cervical Plate System performs comparably with the Synthes CSLP predicate device in mechanical tests.

Summary Basis for Equivalency and Comparison Table:

Mechanical tests of the Sintea Biotech Anterior Cervical Plate System demonstrate that the device is safe and effective for its intended use, and is substantially equivalent to the predicate device (Synthes Spine's CSLP Cervical Spine Locking Plate). The favorable clinical performance of Synthes' CSLP provides additional confirmation that the Sintea Biotech Anterior Cervical Plate System is safe and effective for its intended use. The Sintea Biotech Anterior Cervical Plate System and the referenced predicate devices are similar in that:

- The devices have the same intended use and indications for use.
- The devices are manufactured from the same material.
- The mode of fixation of the devices is similar.
- The devices have similar form, function, components, instruments, geometry, dimensions, features and packaging.
- The devices have the same labeling and sterilization method.
- The devices perform comparably in mechanical tests.

The use of QSR-based process design controls, process controls, testing standards, material standards and similarities to the predicate device establish that the Sintea Biotech Anterior Cervical Plate System is substantially equivalent to Synthes Spine's CSLP, and that it is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 2004

Isabella Elias
Regulatory Affairs Associate
Sintea Biotech, Inc.
407 Lincoln Road, Suite 10L
Miami Beach, Florida 33139

Re: K041989
Trade/Device Name: Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: July 10, 2004
Received: July 23, 2004

Dear Ms. Elias:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4692. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): N/A

Device Name: Sintea Biotech Anterior Cervical Plate System

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- Spinal stenosis
- Deformities or curvature (scoliosis, kyphosis, lordosis)
- Tumor
- Pseudarthrosis
- Failed previous fusion

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
Page 1 of _____

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041987